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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,993	11/04/2003	Charles R. Saikley	TS-02-89	6633

30349 7590 09/14/2007

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

NOTIFICATION DATE	DELIVERY MODE
09/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/701,993	SAIKLEY ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-56* is/are pending in the application.

4a) Of the above claim(s) *36-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-35 and 52-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004 and 10 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendments filed on 06/21/2007, amended claim(s) 21, 22, 24, 27, 28, and 29, and new claim(s) 52-56 is/are acknowledged. The current rejections of the claim(s) 21-35 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

2. Claim 21 is objected to because of the following informalities: the positive recitations of "and" in line 3 appears contain a grammatical and/or typographical error. Appropriate correction is required.

3. Claim 21 is objected to because of the following informalities: the positive recitation of "a lancing device including a lancet drive including a spring operatively coupled to said housing..." appears ambiguous and may be structurally interpreted in several ways. The examiner notes for clarity Applicant may have intended to claim "a lancing device including a lancet drive including a spring, *the lancing device* operatively coupled to said housing...". Appropriate correction is required.

4. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The "spring mechanism" of claim 23 appears to duplicate the structure of the "spring" in claim 21 and may render

the claim indefinite. It appears the "spring mechanism" and the "spring" are indeed the same structure and both as claimed are operatively coupled to the housing.

5. Claims 29 and 34-35 are objected to because of the following informalities: the positive recitation of "the device is configured for traveling along a trajectory..." in lines 1-2 appears to claim the entire device travels along a trajectory and may render the claim indefinite. Moreover, the positive recitation of "a trajectory" appears to duplicate the "trajectory" of claim 21 and may render the claim indefinite. The examiner notes for clarity Applicant may have intended to claim "the *lancing* device is configured for traveling along a *lancing* trajectory...". Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 27 and 52-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a naturally occurring phenomenon (i.e. parts of the human body). The claims positively recite structural limitations of naturally occurring phenomenon, including: a "bodily fluid sample compris(ing)" a submicroliter volume, a volume of less than 1/3 of a microliter, and a diameter of not more than approximately 0.005 inches within the scope of the invention.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 21-35 and 52-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (US 6,306,104 B1, hereinafter Cunningham).

10. For claims 21 and 23, Cunningham discloses a device (10, 900, 1000) for obtaining and testing a bodily fluid sample, comprising:

- a housing (12) defining a first aperture (33);
- a lancing device (16, 67, 908, 1016) including a lancet drive (60) including a spring (68), the lancing device operatively coupled to said housing for obtaining the bodily fluid sample by advancing through said first aperture, piercing a bodily fluid sample location (column 6 lines 17-30 and column 9 lines 29-57), and withdrawing to provide access to the bodily fluid sample by a test strip (914, 1014); and
- a mount block (903, 1003) coupled with a connector that is coupled with a motor (column 32 line 55 – column 33 line 39) within the housing, the mount block configured for coupling the test strip thereto (as best seen in Figures 13-14), wherein the motor moves the mount block and test strip along a trajectory such that a reagent receiving portion (column 7 line 65 – column 8 line 36 and column 16 lines 40-56) of the test strip comes to rest at a center of the bodily fluid sample without moving the housing relative to the bodily fluid sample location (column 32 line 55 – column 33 line 39) (as best seen in Figure 13E), and
- wherein after said lancing and withdrawing of the lancing device, the test strip is movable to a bodily fluid sample contacting position (column 32 line 55 – column 33 line 39), said bodily fluid sample contacting position capable of being within 0.010 inches of said center of said bodily fluid sample.

11. For claim 22, Cunningham discloses the device of claim 21, wherein the lancing device comprises a cutting edge (the at least one lancet in column 6 lines 17-30 and column 9 lines 29-57) that is aligned with the test strip, although withdrawn following lancing to provide said bodily fluid sample, when the test strip is received in the housing and moved to said center of the bodily fluid sample (as best seen in Figure 13E).

12. For claim 24, Cunningham discloses the device of claim 21, wherein the lancing device comprises a body having a first axis, and a sharp operatively connected to the body, wherein the sharp has a second axis that is substantially perpendicular to the first axis (column 6 lines 17-30 and column 9 lines 29-57).

13. For claim 25, Cunningham discloses the device, wherein the lancing device comprising a sharp with at least two points (column 6 lines 17-30 and column 9 lines 29-57).

14. For claim 26, Cunningham discloses the device, wherein the lancing device is of a construction sufficient to pierce tissue of a patient (column 6 lines 17-30 and column 9 lines 29-57).

15. For claims 27 and 52-56, Cunningham discloses the device, wherein the bodily fluid sample is capable of comprising a submicroliter volume, a volume of less than 1/3 of a microliter, and a diameter of not more than approximately 0.005 inches.

16. For claim 28, Cunningham discloses the device, wherein when the test strip is in the bodily fluid sample-contacting position, a fill channel (column 7 line 65 – column 8 line 36 and column 16 lines 40-56) of the test strip is capable of being aligned with the sample within 0.005 inches of said center of said sample (as best seen in Figure 13E).

17. For claims 29, 34, and 35, Cunningham discloses the device, wherein the lancing device is capable of traveling along a trajectory of 0.03 inches along the bodily fluid sample location at an approach angle between 35 – 65 degrees.

18. For claim 30, Cunningham discloses the device, wherein the physiological property that is determined from the sample comprises a glucose level (Abstract).

19. For claim 31, Cunningham discloses the device, further comprising a controller (20) operatively coupled to the housing for controlling operation of the lancing device (column 13 lines 33-51).

20. For claim 32, Cunningham discloses the device, further comprising an input unit (1009) operatively coupled to the housing for operating the lancing device.

21. For claim 33, Cunningham discloses the device, further comprising a controller (20) operatively coupled to the housing for controlling movement of the test strip when the test strip is received in the housing (column 32 line 55 – column 33 line 39).

Response to Arguments

22. Applicant's arguments filed 06/21/2007 with respect to claims 21-35 and 52-56 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

MAX F. HINDENBURG
PRIMARY PATENT EXAMINER
TECHNOLOGY CENTER 3700